

SEP 22 1998

510(k) Premarket Notification  
K973722  
BIONECT® Hydrogel Foam  
Amendment No. 3

**fidia** Pharmaceutical Corporation

July 9, 1998

## **10. 510(k) SUMMARY**

### **10.1 Summary Information**

#### **10.1.1 Submitter's name and address**

FIDIA Pharmaceutical Corporation  
2000 K Street, NW, Suite 700  
Washington, DC 20006

Contact person and telephone number:

Roberto Fiorentini, M.D., President  
Telephone: (202) 371-9898  
Telefax: (202) 371-1666

Date summary was prepared:

July 9, 1998

#### **10.1.2 Name of the Device**

Trade Name:	BIONECT® Hydrogel Foam
Common Name:	Hyaluronic acid sodium salt hydrogel dressing
Classification Name:	Hydrogel Wound and Burn Dressing

#### **10.1.3 Identification of predicate device to which substantial equivalence is being claimed**

BIONECT® Hydrogel Foam is substantially equivalent in function and intended use to the following cleared non-interactive wound and burn dressing: BIONECT® Hydrogel.

#### **10.1.4 Device description**

Explanation of how the device functions: BIONECT® Hydrogel Foam, since it is a hydrogel dressing, provides a soothing, moist environment that is supportive to wound healing.

**fidia** Pharmaceutical Corporation

July 9, 1998

Basic scientific concepts that form the basis for the device: BIONECT® Hydrogel Foam, since it is a hydrogel dressing, provides a soothing, moist environment that is supportive to wound healing.

Significant physical and performance characteristics of the device such as device design, materials used, and physical properties: BIONECT® Hydrogel Foam is a white foam that is prepared from sodium hyaluronate and purified water to form a hydrogel dressing. Sodium hyaluronate is a polysaccharide biopolymer that can increase the viscosity of the gel. BIONECT® Hydrogel Foam, since it is a hydrogel dressing, provides a soothing, moist environment that is supportive to wound healing.

**10.1.5 Statement of the intended use of the device, including general description of the conditions the device will mitigate and the patient population for which the device is intended**

BIONECT® Hydrogel Foam is indicated for the dressing and management of partial to full thickness dermal ulcers (pressure sores, venous stasis ulcers, arterial ulcers, diabetic ulcers), wounds including cuts, abrasions, donor sites, and post-operative incisions, irritations of the skin, and first and second degree burns.

These indication statements are not substantially different from the predicate device identified in Section 10.1.3.

**10.1.6 Statement of how the technological characteristics of the device compare to those of the predicate device**

The technological characteristics of the device such as occlusion, bioburden level, and moist wound healing are not different from the predicate device cited.

**10.2 Assessment of performance data**

*In vitro and in vivo* biocompatibility testing (cytotoxicity, dermal irritation, and dermal sensitization tests) has been performed on the bulk solution that impregnates BIONECT® Hydrogel Foam in accordance with FDA recommendations.<sup>5</sup> These tests all support the safe use of BIONECT® Hydrogel Foam as a hydrogel temporary dressing in contact with breached or compromised skin.

---

<sup>5</sup> Office of Device Evaluation General Program Memorandum #695-1, International Standard ISO-10993, "Biological Evaluation of Medical Devices part 1: Evaluation and Testing," dated 1 May 1995.

**fidia** Pharmaceutical Corporation

July 9, 1998

---

Clinical experience with BIONECT® Hydrogel and BIONECT® Hydrogel Gauze Pads in 22 clinical trials (17 controlled) conducted in Europe in patients with various types of ulcers, burns, and surgical wounds indicates that BIONECT® Hydrogel Foam is safe for its intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 22 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Roberto Fiorentini, M.D.  
President  
Fidia Pharmaceutical Corporation  
2000 K Street, N.W., Suite 700  
Washington, D.C. 20006

Re: K973721, K973722, K973724 and K973725  
Trade Name: Bionect Hydrogel Gauze Pads, Bionect Hydrogel Foam  
Bionect Hyrdogel Spray and Bionect Clear Hydrogel  
Regulatory Class: Unclassified  
Product Code: MGQ  
Dated: July 1 and July 8, 1998  
Received: July 1 and July 9, 1998

Dear Dr. Fiorentini:

We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are substantially equivalent (for the indications for use stated in the enclosures) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act). You may, therefore, market your devices subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) and the following limitations:

1. These devices may not be labeled for use on third degree burns.
2. These devices may not be labeled as having any accelerating effect on the rate of wound healing or epithelization.
3. These devices may not be labeled as a long-term, permanent, or no-change dressing, or as an artificial (synthetic) skin.
4. These devices may not be labeled as a treatment or a cure for any type of wound.

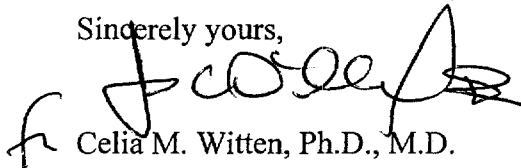
The labeling claims listed above would be considered a major modification in the intended use of the devices and would require a premarket notification submission (21 CFR 807.81). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

If your devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval) they may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations (CFR), Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practices (GMP) for Medical Devices: General GMP regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your devices in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your devices, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or 301-443-6597 or at its internet address <http://www.fda.gov/cdrh/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'C. Witten', with a stylized flourish at the end.

Celia M. Witten, Ph.D., M.D.  
Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosures

510(k) Premarket Notification  
K973722

BIONECT® Hydrogel Foam  
Amendment No. 3

**fidia** Pharmaceutical Corporation

July 9, 1998

## 2. INDICATIONS FOR USE

510(k) Number (if known): K973722

Device Name: BIONECT® Hydrogel Foam  
Indications for Use:

BIONECT® Hydrogel Foam is indicated for the dressing and management of partial to full thickness dermal ulcers (pressure sores, venous stasis ulcers, arterial ulcers, diabetic ulcers), wounds including cuts, abrasions, donor sites, and post-operative incisions, irritations of the skin, and first and second degree burns.

✓ prescription

  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K973722

Prescription Use ✓  
(Per 21 CFR 801.109)